OCTA | Office of Clinical Trials Administration

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The Office of Clinical Trials Administration (OCTA) has the responsibility and authority to negotiate and execute agreements that meet the above definition of a clinical trial when (i) under an industry developed protocol and (ii) funded by industry. Such industry sponsor-initiated and funded clinical trials are authored and funded by a pharmaceutical, device, biotech company, or for-profit Clinical Research Organization (CRO) whether directly or indirectly through another academic medical center or non-profit organization.The Office of Contract and Grant Administration (OCGA) has the responsibility and authority to negotiate and execute a broader spectrum of research agreements, including UCSD Investigator authored clinical trial protocols and clinical trials funded by the government or a non-profit entity.

Effective August 1, 2016, the OCTA Clinical Trial Agreement Request Form will no longer be used. All Health Science departments have been onboarded to ePD. Clinical trials must be submitted to ePD.

Training and Approval Access is ***required*** for the proposal creators in order to create a new Clinical Trial proposal in ePD at: http://blink.ucsd.edu/research/preparing-proposals/proposal-development/epd/access-use.html

For questions, please contact OCTA@ucsd.edu or **858-822-2940**.

Last updated: 29 Aug 2019

Office of Clinical Trials Administration (OCTA)

ASSIGNMENT BY - LEAD DEPARTMENT* (for all Contract Types)	Contract Officer
Alzheimers (ADCS)	Leah Williams
Anesthesiology	Leah Williams
Cancer Center (includes Hem-Onc/BMT)	Sanaz Masha; David Beatty
Cardiology	Lindsey Wholey
Cardiovascular Medicine (DOM)	Lindsey Wholey
Dermatology/Peds Dermatology	Kelly Quintana

Emergency Medicine	Leah Williams
Endocrinology & Metabolism (DOM)	Lindsey Wholey
Family Medicine and Public Health	Leah Williams
Gastroenterology (DOM)	Lindsey Wholey
Geriatrics (DOM)	Lindsey Wholey
Hematology (through DOM/non-MCC)	Leah Williams
Infectious Diseases (DOM)	Leah Williams
Internal Medicine (DOM)	Lindsey Wholey
Medicine/Hospital Medicine (DOM)	Lindsey Wholey
Nephrology (DOM)	Leah Williams
Neuroscience	Leah Williams
Ophthalmology	Leah Williams
Orthopedic Surgery	Leah Williams
Pathology	Leah Williams
Pediatrics	Leah Williams, Kelly Quintana, Lauren Sanfilippo
Psychiatry	Kelly Quintana
Pulmonary (DOM)	Lindsey Wholey
Radiology	Leah Williams
Regenerative Medicine (DOM)	Lindsey Wholey
Reproductive Medicine	Leah Williams
Rheumatology, Allergy & Immunology (DOM)	Lindsey Wholey
Surgery	Kelly Quintana
Urology	Leah Williams**

*Lead Department is the department through which the study is being submitted/conducted, which may differ from PI's home department.

****Any Department not covered by this list will be assigned to Leah Williams**

DOM = a division within the Department of Medicine (will appear as "Medicine" in ePD, Coeus, and OCTA Application)

Glossary

CDA	Confidential Disclosure Agreement
COI	Conflict of Interest
CRO	Contract Research Organization – an organization that provides support to pharmaceutical companies in administering a clinical study
CTA	Clinical Trial Agreement
DBO	Direct Business Officer
ePD	Electronic Proposal Database
HRPP	Human Research Protections Program
IRB	Institutional Review Board
MSO	Management Services Officer
NDA	Non-Disclosure Agreement
OCAA	Office of Coverage Analysis Administration
OCTA	Office of Clinical Trials Administration
PI	Principal Investigator
Sponsor	A for-profit entity that initiates and takes responsibility for a clinical investigation
Study team	Principal Investigator, co-Investigator(s), Project Manager(s), study coordinator(s), regulatory personnel, and fund manager(s)

Last updated: 29 Aug 2019

Payment Methods

For information regarding payments, see OCTA Financial or e-mail OCTAFinancials@ucsd.edu.

Last updated: 20 Mar 2019

ACTIONS | OCTA

PRE-AWARD PROCESS

The OCTA Contract Officer will:

- Contact the sponsor to initiate contract negotiations;
- Provide the sponsor with the standard UCSD agreement if a sponsor agreement is not provided;
- Obtain a copy of previous agreement (if applicable);
- Review and propose revisions to the contract;
- Negotiate final revisions to the contract;
- Forward the final agreement to the Principal Investigator for signature (the PI will then send the signed contract back to the OCTA contract Officer);
- Sign the Agreement on the behalf of The Regents;
- Forward the signed contract to the Sponsor (the Sponsor will then sign the signed contract back to the contract negotiator).

Once the appropriate paperwork has been submitted, please check the OCTA Dashboard for the in-process status and notes about the study.

CONTRACT NEGOTIATIONS

Negotiations involving a contract can sometimes be quite complex and lengthy, depending upon the sponsoring organization and the nature of the work to be performed.

Contracts with clinical trial sponsors (e.g., pharmaceuticals or medical device companies, clinical research organizations) cover human testing activities related to an investigational drug, compound or device leading to approval by the Food and Drug Administration for commercial distribution.

As a public, nonprofit educational institution, the University is bound by certain policies and regulations regarding what it can and cannot accept in a clinical trial contract. These policies are designed to protect the welfare of individuals participating as research subjects; foster the University's basic mission of teaching, research and public service; and minimize the various forms of liability associated with human subject research.

For-profit private sponsors, such as pharmaceutical companies, are motivated by different forces than the University. As a result, they sometimes do not understand the ideals and principals behind our policies. Consequently, additional time may be required for contract negotiations while the contracts negotiator works with the sponsor to arrive at a mutually acceptable agreement.

When negotiating clinical trial contracts, the University primarily focuses on securing acceptable contract clauses regarding high-risk issues such as subject injury, indemnification, confidentiality, ownership of data, patent rights and

publication rights.

The University's standard clinical trial agreement and the clauses proposed by the University during contract negotiations are based on the following assumptions:

- That the clinical investigation is conducted under a protocol that is a FDA Phase I, II, III, or IV drug study or a FDA regulated medical device study.
- That the Sponsor provides its proprietary product and study protocol to the University for the purpose of conducting a clinical trial; and
- That the sponsor will fully fund the cost of the trial (i.e., no work will be supported in whole or in part with other fund, including Federal funds).

POST-AWARD PROCESS

- The index number will be assigned within 1 business day
- Distribution of a copy of the executed agreement to the Principal Investigator and study team will be included with the index number

CONTRACT AMENDMENTS

Amendments, modifications, and Addenda should be entered into the OCTA Application: http://som.ucsd.edu/OCTAApplication

Last updated: 15 Mar 2019

Once a study has received IRB approval and has a fully executed CTA, the OCTA financial team will set up your index. This process usually takes place within 24 business hours of contract execution (if the study is IRB approved). This study-specific index is where you will be able to manage your study related expenses in accordance with UC policy. The generated index will be linked to the research account (formerly "Bulk Account") for each study. We recommend completing the research account application when submitting to the IRB and completing the CTA form. For assistance completing the Research Account application please contact ctri-velos@ucsd.edu.

If you are member of a study team and your role requires you to be notified of the index setup, please send us an email to OCTAFinancials@ucsd.edu with your contact information and study details, and we will be happy to add you to the notifications list.

Last updated: 7 Mar 2018

Confidential Disclosure Agreements (CDA) or Non-Disclosure Agreement (NDA)

The first step in initiating a clinical trial is obtaining the protocol from the sponsor or the Contract Research Organization (CRO). Usually before the sponsor or the CRO is willing to release a copy of the confidential protocol, they will require that a Confidential Disclosure Agreement (CDA) be signed. The CDA should be signed by a University representative on behalf of its employee, the potential investigator. Note that the OCTA only handles NDAs for sponsor-initiated trials.

As soon as the potential investigator receives the CDA, it should be entered into the OCTA Application, http://som.ucsd.edu/OCTAApplication along with the contact information for the sponsor or CRO. The OCTA analyst will then review the CDA to ensure the terms and conditions of the document are in compliance with

University policies. Should revisions be necessary, the OCTA analyst will contact the sponsor or CRO to negotiate language acceptable to both parties. To ensure any unnecessary delay in getting the protocol to the potential investigator, the initial sponsor or CRO contact, the CDA review will occur within 24-72 hours of the OCTA receiving the CDA.

Problem areas with CDA's may include:

- Sponsor Ownership of Intellectual Property arising out of the trial;
- Potential investigator indemnifies sponsor for breach of confidentiality;
- Governing law is a state other than California;
- No end date to the CDA;
- Publication restrictions

After the CDA is signed and the potential investigator receives the protocol, s/he will determine the feasibility of conducting the clinical trial at UC San Diego.

Some of the issues that should be considered are:

- Does the investigator have the necessary patient population;
- Is the protocol well designed;
- Are the study timelines reasonable;
- Does the investigator's staff have the time to take on another study.

Once the decision is made to conduct the clinical trial, **the investigator should start the IRB submission and (in parallel) submit the appropriate paperwork to OCTA. Please be prepared to provide OCTA with the IRB number.**

Last updated: 18 Sep 2019

Last updated: 20 Mar 2019

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